SYNTHES®

K041911

SEP - 8 2004

3.0 510(k) Summary

Sponsor:
Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes LCP® Curved Plates

Classification: 21 CFR 888.3030: Single/Multiple component metallic bone fixation appliances and accessories

Predicate Devices: Synthes Large Fragment Dynamic Compression System
Synthes Locking Condylar Plating System

Device Description: The Synthes LCP® Curved Plates have a slight curve to better match the anatomy of the bone. The plates have a limited contact profile design and includes combination dynamic compression/locking screw holes.

Intended Use: The Synthes **Curved Broad Plates** are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of peri-prosthetic fractures, osteopenic bone and non-unions or malunions.

The Synthes **Curved Condylar Plates** are intended for buttressing multifragmentary distal femur fractures, including : supracondylar, intra-articular and extra-articular condylar fractures, peri-prosthetic fractures and fractures in normal or osteopenic bone, nonunions/malunions, and osteotomies of the femur.

Substantial Equivalence: Comparative information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2004

Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pensylvania 19301

Re: K041911
Device Name: Synthes (USA) LCP® Curved Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: July 13, 2004
Received: July 15, 2004

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

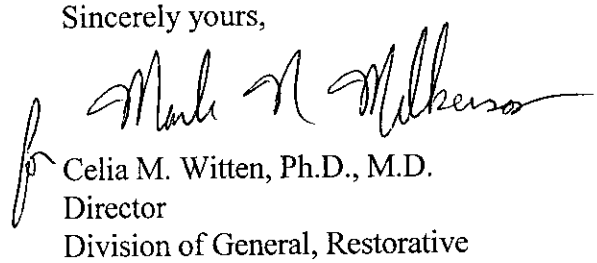
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 **Indications for Use**

510(k) Number (if known): K041911

Device Name: Synthes (USA) LCP® Curved Plates

Indications for Use:

The Synthes **Curved Broad Plates** are intended for fixation of various long bones, such as the humerus, femur, and tibia. They are also for use in fixation of peri-prosthetic fractures, osteopenic bone and non-unions or malunions.

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Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041911

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)